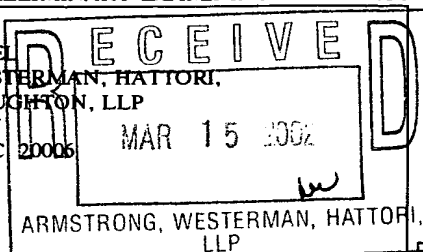


PATENT COOPERATION TREATY

NES

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
NICOLAS E. SECKEL
ARMSTRONG, WESTERMAN, HATTORI,
MCLELAND & NAUGHTON, LLP
1725 K STREET NW
WASHINGTON, DC 20006



PCT

Response to
Written Opinion
Due: May 12, '02

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference 000152PCT		Date of Mailing (day/month/year) 12 MAR 2002 REPLY DUE within 2 months/days from the above date of mailing
International application No. PCT/US01/09590	International filing date (day/month/year) 26 March 2001 (26.03.2001)	Priority date (day/month/year) 24 March 2000 (24.03.2000)
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61K 48/00, 38/00, 35/00; C12N 15/63 and US Cl.: 514/2, 44:424/93.21;435/320.1		
Applicant TKACHUK, ZENOVY		

1. This ~~written opinion~~ is the first (first, etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 24 July 2002 (24.07.2002).

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Q. Janice Li Telephone No. 703-308-0196
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Form PCT/IPEA/408 (cover sheet)(July 1998)

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3-15-02

WRITTEN OPINION

International application No.

PCT/US01/09590

I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☒ the description:
 - pages 1-58, as originally filed
 - pages NONE, filed with the demand
 - pages NONE, filed with the letter of _____.
- ☒ the claims:
 - pages 59-62, as originally filed
 - pages NONE, as amended (together with any statement) under Article 19
 - pages NONE, filed with the demand
 - pages NONE, filed with the letter of _____.
- ☒ the drawings:
 - pages none, as originally filed
 - pages NONE, filed with the demand
 - pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
 - pages NONE, as originally filed
 - pages NONE, filed with the demand
 - pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

WRITTEN OPINION

International application No.

PCT/US01/09590

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 14-21

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 14-21 are so unclear that no meaningful opinion could be formed (*specify*):

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule.

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 14-21.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

WRITTEN OPINION

International application No.
PCT/US01/09590

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 30-33	YES
	Claims 1-13, 22-29	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-13, 22-33	NO
Industrial Applicability (IA)	Claims 1-13, 22-33	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-11, and 22-29 lack novelty under PCT Article 33(2) as being anticipated by WO 94/02595.

These claims are directed to method for the treatment of inflammation or inflammatory-related disorder comprising administering to a mammal in need of an effective amount of ribonucleic acid and a pharmaceutically acceptable vehicle, wherein the inflammatory-associated disorder is infarct, stroke, arthritis, allergy, etc., and the composition used in the method.

WO 94/02595 teaches using an enzymatic RNA molecule for treating inflammatory associated disorders, such as arthritis, psoriasis, and cardiovascular diseases (page 10 and claims 1, 2, 11, and 12). Thus, WO 94/02595 anticipates these claims.

Claims 1-13, 26, and 29 lack novelty under PCT Article 33(2) as being anticipated by US 5,712,256.

These claims are directed to method for the treatment of inflammation or inflammatory-related disorder comprising administering to a mammal in need of an effective amount of ribonucleic acid and a pharmaceutically acceptable vehicle, wherein the inflammatory-associated disorder is pain, and swelling, etc., and the composition used in the method, wherein the dosing ranges from 0.1mg to 1g/kg, or 0.1 to 1 gram.

US 5,712,256 teaches using an enzymatic RNA molecule for treating inflammatory associated disorders, such as wound (claims 1, 2, 3), wherein the sufficient dose is about 0.17g/kg per day (claim 4). Thus, WO 94/02595 anticipates these claims.

Claims 1-13, 22-33 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of US 3,615,654.

Claims 31-33 further drawn to the composition wherein the ribonucleic acid has a nitrogen content of more than 14.5% by weight, and a phosphorus content of more than 8.5% by weight, wherein the pharmaceutical carrier is capsules or suppositories.

US 3,615,654 teaches that pure ribonucleic acids from microbial cells have 8.5% phosphorus and 15.1% nitrogen (column 7, lines 24-25). And the specification teaches to obtain the RNA from microbial cells. Further capsules and suppositories are the commonly used pharmaceutical carriers. Thus, claimed invention, as a whole is obvious over the cited prior art.

Claims 1-13, 22-33 meet the criteria set out for industrial applicability in PCT Article 33(4), because the method could be used treating inflammatory associated disorders.

----- NEW CITATIONS -----

US 3,615,654 A (AYUKAWA, Y) 26 October 1971, column 7, lines 24-25), Relevant to claims 31 and 32.

WRITTEN OPINION

International application No.
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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.